Safe-to-Fly Test and Evaluation of Fatigue Research Study Test Devices

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Introduction: The U.S. Air Force (USAF) School of Aerospace Medicine is conducting a fatigue research study titled "Assessment of Fatigue in Deployed Critical Care Air Transport Team (CCATT) Crews" using two electronic devices onboard USAF aircraft during actual CCATT missions. Both devices were subjected to testing to support a safe-to-fly (STF) recommendation prior to their use in flight. The purpose of the test and evaluation process was to ensure the devices can be safely operated in flight without posing a hazard to the research participant, crewmembers, or aircraft during an actual mission. The goal of this article is to outline the key factors involved in the STF certification process. ***Methods:*** This paper discusses the test and evaluation process for making STF recommendation and presents the rationale for selecting the applicable tests and test susceptibilities. The following STF tests were conducted: baseline assessment, vibration, electromagnetic interference, altitude, rapid decompression, and explosive atmosphere. Acceleration testing, environmental (temperature and humidity) testing, and in-flight assessments were deemed not required for the STF certification of these devices. ***Results:*** Based on the results of this study, the devices were deemed safe to the flight crew and aircraft. ***Conclusions:*** The outcome of this study was subsequent approval letters issued by the respective airframe system program offices to allow use of these devices onboard USAF C-130 E/H/J, C-17, and KC-135 aircraft.

Keywords: aeromedical flight testing, aviation fatigue, CCATT.

THE DEPARTMENT of Aeromedical Research at the U.S. Air Force (USAF) School of Aerospace Medicine, Wright-Patterson Air Force Base (WPAFB), is conducting a fatigue assessment study on Critical Care Air Transport Team (CCATT) personnel titled "Assessment of Fatigue in Deployed CCATT Crews." This study includes an in-theater activity monitoring phase to identify sleep patterns and collect subjective and objective fatigue data on the participants. In support of this project, the Surgeon General's office at Air Mobility Command tasked the USAF Agile Combat Support Directorate, Aeromedical Branch, Aeromedical Test Lab (ATL) for safe-to-fly (STF) testing of a PDA and actigraph to ensure compatibility with aircraft and mission requirements.

These types of devices are commonly used for ground-based fatigue field studies (3,14). Similar methods have been proposed and used in fatigue studies in commercial aviation when commercial flight attendants were studied (13,16,18). A search of the literature did not reveal any other research study in military aviation to use these devices. Therefore, the devices must undergo testing to ensure that they do not adversely affect the operation of aircraft systems and that the aircraft systems do not adversely affect the proper operation of the devices.

In general, medical devices are designed to function in environmentally controlled locations, such as stationary hospitals, and not in the harsh, dynamic aircraft environment. Yet, the same medical devices used to care for patients in a hospital environment are often the most capable devices for patient care during transport from one location to another. Often referred to as medical evacuation (medevac) and aeromedical evacuation (AE) missions, these missions supply the means to provide en route medical care to a wide variety of patients. However, since medical devices are often designed for stationary, controlled facilities, there is the chance the devices may adversely affect aircraft operations and, conversely, the aircraft may adversely affect the operation of the medical equipment (12). Additionally, all medical equipment, including research devices, identified for use on USAF fixed-wing aircraft must undergo STF evaluation in accordance with Section 2.5.1.7 of Air Force Instruction (AFI) 11-2AEV3, General Flight Rules (20), before the STF certification can be issued by the authorizing aircraft system program offices. Military and civilian standards, regulations, and specifications, as well as professional experience and expertise, are all part of the STF test and evaluation process.

The aeromedical equipment STF test process starts with receiving a formal letter from the requesting agency: Air Mobility Command. **Fig. 1** describes the STF test process in an activity flow diagram. The activities of the ATL are shown in the second column. If the manufacturer of a test article does not have Food and Drug Administration (FDA) clearance at the time of testing, testing may commence; however, an STF recommendation letter is sought until the manufacturer shows evidence of FDA clearance (12). Medical equipment that is under testing and evaluation is expected to have an identification

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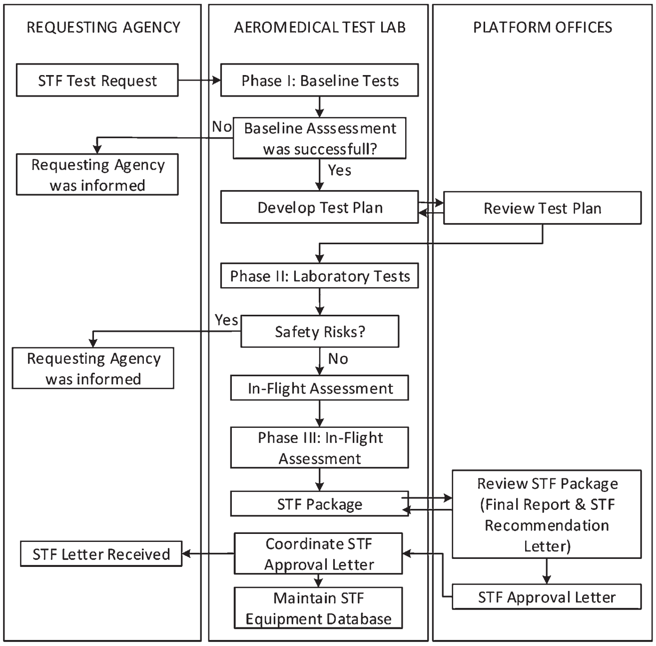

Fig. 1. Aeromedical equipment safe-to-fly test process.

marking, preferably using MIL-STD-130N as guidance (10).

A typical STF evaluation generally has three phases: baseline assessment, laboratory testing, and in-flight assessment. The phases of the STF test activities are shown in **Fig. 2**. The purpose of the baseline assessment is to verify that the equipment under test (EUT) operates in accordance with the manufacturer's specifications; that it applies human factors design standards, per MIL-STD-1472F (9); that it is electrically safe; that proper tie down has been identified; and that it operates and integrates with the aircraft, both on the ground and in flight. The test personnel use ANSI/AAMI ES60601-1:2005 – medical electrical equipment, part 1: general requirements for basic safety (1) and essential performance or National Fire Protection Association 99 as guidance for electrical safety tests (15). For electric generator or converter equipment such as frequency converters that will be used for powering aeromedical medical equipment in USAF aircraft, the equipment's electrical generating characteristics will be evaluated for the aircraft's electrical power interface using MIL-STD-704F (5) and MIL-HDBK-704 (8) as guidance. The baseline assessment also familiarizes test personnel with the operation and characteristics of the device.

The purpose of laboratory testing is to simulate the Department of Defense operational environment through testing, modeled after a series of worst-case event scenarios. There are two overall goals for all laboratory tests as follows: 1) identify the potential safety concerns that the article may pose for the aircraft, patient, and aircrew; and 2) identify the physical or functional degradation that the test article may experience within the en route care environment. Fig. 2 shows laboratory tests performed for typical medical equipment. In general, MIL-HDBK-516B establishes the airworthiness certification criteria to be used as guidance for defining certification requirements (6). All components, including aeromedical equipment, either individually or as part of a subsystem, must be verified to pass all safety-related qualification tests. The test items, for example vibrations, temperature, rapid decompression, etc., are listed in Fig. 2 and they are used to assess aeromedical equipment. The tests are identified using environmental concerns and specific platform requirements. The

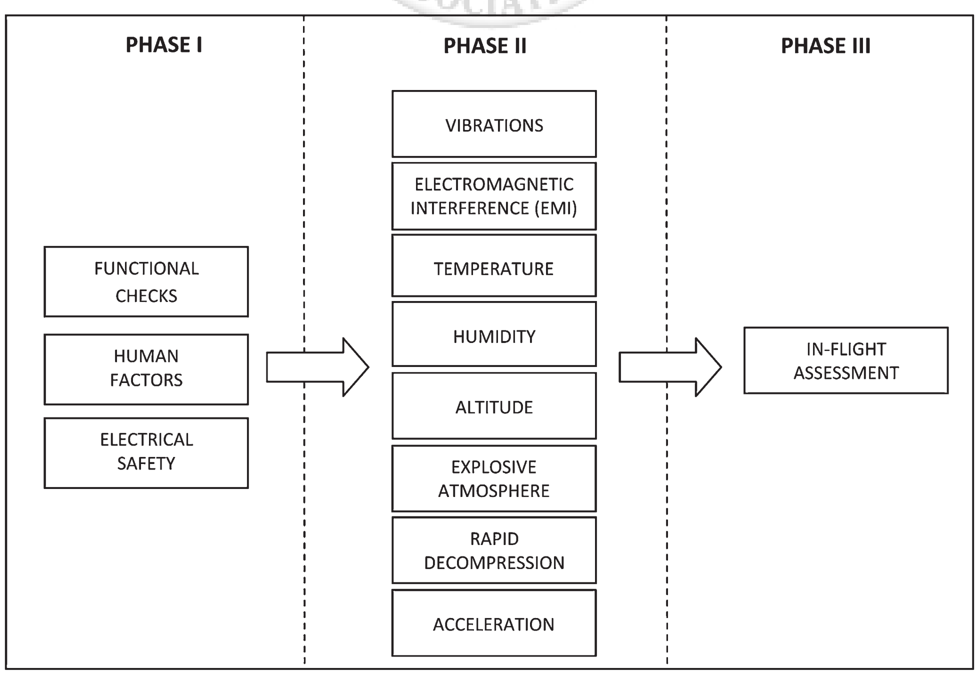

Fig. 2. Phases of the safe-to-fly test activities for typical aeromedical test equipment.

test procedures are usually derived from military standards, such as MIL-STD-810G (7), and methods are described in detail in a recently published document called Joint Enroute Care Equipment Test Standard (JECETS) (12).

Laboratory test findings are assessed by subject matter experts (SMEs), engineers, and AE aircrew. Anomalies are evaluated with respect to aircraft, aircrew, and patient safety. Anomalies to full compliance are identified and assessed by the SME panel to determine if the resultant safety risk should be accepted before or after mitigation. Mitigation measures are often limitations on use which are conveyed in the STF recommendation letter.

During the in-flight assessment, the test article is evaluated during USAF AE training missions by actual crewmembers to validate laboratory findings and assess human factors during in-flight operation. Proper clinical function, placement, and aircraft interfaces (e.g., oxygen, electrical, and litter support systems) of the equipment are evaluated during the airborne assessment using AFI 10-2909 (19), Aeromedical Evacuation Equipment Standards; AFI 11-2AE, Volume 3, AE Operations Procedures (20); and AFI 11-202, Volume 3, General Flight Rules (21). Crew member feedback is solicited to identify issues regarding equipment form, fit, and function, as well as to ensure safe and effective clinical operation.

The authors completed all tests required for the STF recommendation for the PDA and the actigraph. This paper presents a record of test results and evaluation of the results for recommendation of these devices for USAF fixed-wing (C-17, C-130E/H, C-130J, and KC-135) AE aircraft STF approval. These approvals allow for use of the devices onboard USAF AE aircraft. Furthermore, the goal of this article is to outline the key factors involved in the STF certification process. This goal is accomplished by reporting on each required step as it related to the devices evaluated in this study.

METHODS

The JECETS (12) provides the test procedures for testing of medical equipment for use onboard joint platforms (i.e., where the mission requires using the device first onboard a U.S. Army helicopter and then onboard a USAF fixed-wing aircraft). Both devices were exposed to and met the following relevant tests per the JECETS: baseline assessment, vibration, electromagnetic interference (EMI), altitude, rapid decompression, and explosive atmosphere. Acceleration testing, environmental (temperature and humidity) testing, and in-flight assessments were deemed not required for the EUT devices.

The AT&T Tilt PDA (Dallas, TX) and the Respironics Actiwatch 2 actigraph (Murrysville, PA) were the research devices being tested. The PDA is a mobile device used as a personal information center to provide the user access to preloaded fatigue assessment applications (2). The actigraph is a wrist-worn device that monitors activity and collects data that can be used to infer sleep/rest cycles (17).

Test setup and performance check procedures were developed to verify the EUT was functioning properly under various testing conditions. Specific tests were identified to verify the EUT devices functioned in accordance with manufacturers' specifications while being exposed to the simulated aircraft environments. These tests include the baseline assessment and vibration tests at the ATL at Wright-Patterson AFB, the EMI tests at Wright-Patterson AFB, the altitude and rapid decompression tests at Wyle Labs, Brooks City-Base, TX, and the explosive atmosphere tests at Warner Robins AFB, GA. The Results and Discussion sections elaborate on the specific tests the units underwent. The test procedures were tailored using JECETS procedures (12) to the airframes (C-130s, C-17, and KC-135) where the devices will be used. The EUT devices were tested to ensure that they did not experience the following susceptibilities:

1. Loss of data collection during tests.
2. Loss of data transfer capability after the test (simulating post-flight data download).
3. Power loss.
4. Faulty and unintended operation of the EUT.
5. Permanent damage to device, leading to inoperable status.
6. Other unexpected system degradation or malfunctions.

RESULTS

Baseline Performance

Baseline assessments on the PDA and the actigraph were conducted at WPAFB. The initial inspection verified that the EUT devices were not damaged and were fully functional as advertised by the manufacturer. Lab personnel performed the fatigue measurement tasks and wore the actigraph to check functionality for a 2-d period of time. The results showed that the EUT devices were efficient, accurate, easy to use, and fully functional as described in the owner's manuals.

A standardized checklist based on MIL-STD-1472F (9) criteria that consider the visual display, audio warnings, device labels, maintenance of the unit, and safety hazards was used for the human factors check. ATL personnel performed human factors assessment on the EUT devices and did not observe any notable issues.

Mission requirements state that the PDA battery must last at least 48 h without being recharged. Research participants were instructed to leave the PDA turned off and only turn it on when required to complete a fatigue assessment session (three times per mission: pre-mission, during the mission, and post-mission). During the operational assessment of this device, the battery life lasted 8.5 d when used in this manner, once each day. The power adapter/charger of the PDA device will be transported during flights; however, the users will be instructed not to plug it into the aircraft power. As recommended by the KC-135 aircraft System Program Office personnel during the test plan review, all 15 adapter/charger devices were labeled "do not plug into the aircraft power."

The operational mode for this research project was ambient light and motion data collection every 30 s. The

mission requirement for the battery life of the actigraph is that the battery must last at least 14 d; the manufacturer states that the battery life is 15.2 d for this configuration. A battery check was completed and it was verified that the battery would collect data in this configuration for at least 14 d. In addition to the actigraph data to infer the sleep/rest cycle of the participant, each individual also be completed a sleep log, which was used to corroborate the conclusions from the actigraph data.

Aircraft Vibrations

Typical MIL-STD-810G (7) aircraft vibration tests were deemed not required for the PDA because it will be stored in the research participant's pocket. However, the authors conducted vibration tests using the actigraph to identify the effect of the aircraft's ambient vibrations on the data being recorded. Vibration tests were conducted in the ATL at WPAFB to determine if the actigraph recording would be affected when it was exposed to aircraft vibration. For example, if a research participant is sleeping during flight, it is helpful to know whether the nominal aircraft vibrations recorded by the actigraph suggest the subject was awake. **Fig. 3** displays the data collected from the actigraph during the test. These results indicated that when interpreting actigraph data collected on an aircraft, the minimum activity count threshold may need to be adjusted to infer whether or not a research participant is resting at that time. Data collected as part of this effort will assist investigators in determining the activity threshold for data collected during flight.

Electromagnetic Interference

The purpose of EMI testing was to determine the electromagnetic characteristics of the EUT devices and verify that the devices will not radiate electromagnetic signals that could interfere with other equipment or systems/subsystems onboard the aircraft. An additional objective of these tests was to ensure that the EUT devices were not be susceptible to radiated fields, causing equipment malfunctions. The U.S. Air Force EMI Research Laboratory conducted EMI tests using MIL-STD-461F Radiated Emissions (RE) Method 102 and Radiated Susceptibility (RS) Method 103 (11). The measurements were performed in a 20-ft × 18-ft × 10-ft (6.1-m × 5.5-m × 3-m) shielded room. The room is treated with anechoic material in accordance with MIL-STD-461F (11) requirements. Most test instrumentation was located in a separate shielded control room.

The EUT devices were tested to meet USAF aircraft requirements using the following specific RE102 test procedures (11):

1. 2–8 MHz;
2. 8–30 MHz;
3. 30–90 MHz, Antenna Polarity: Horizontal & Vertical;
4. 90–120 MHz, Antenna Polarity: Vertical & Horizontal;
5. 120–200 MHz, Antenna Polarity: Horizontal & Vertical;
6. 200–400 MHz, Antenna Polarity: Vertical & Horizontal;
7. 400–1000 MHz, Antenna Polarity: Vertical & Horizontal;
8. 1–2 GHz, Antenna Polarity: Vertical & Horizontal;
9. 2–4 GHz, Antenna Polarity: Vertical & Horizontal;
10. 4–8 GHz, Antenna Polarity: Vertical & Horizontal;
11. 8–12 GHz, Antenna Polarity: Vertical & Horizontal; and
12. 12–18 GHz, Antenna Polarity: Vertical & Horizontal.

Because of the airframes in which the devices will be used, radiated emission tests included RE102-3, which is the test method subpart for USAF fixed-wing aircraft with nose to tail distance longer than 82 ft (25 m). Additionally, both the EUT devices passed the 20-V/m requirement from 500 MHz to 1 GHz and 60-V/m requirement from 1 GHz to 8 GHz using the RS103 test procedure per MIL-STD-461F (11).

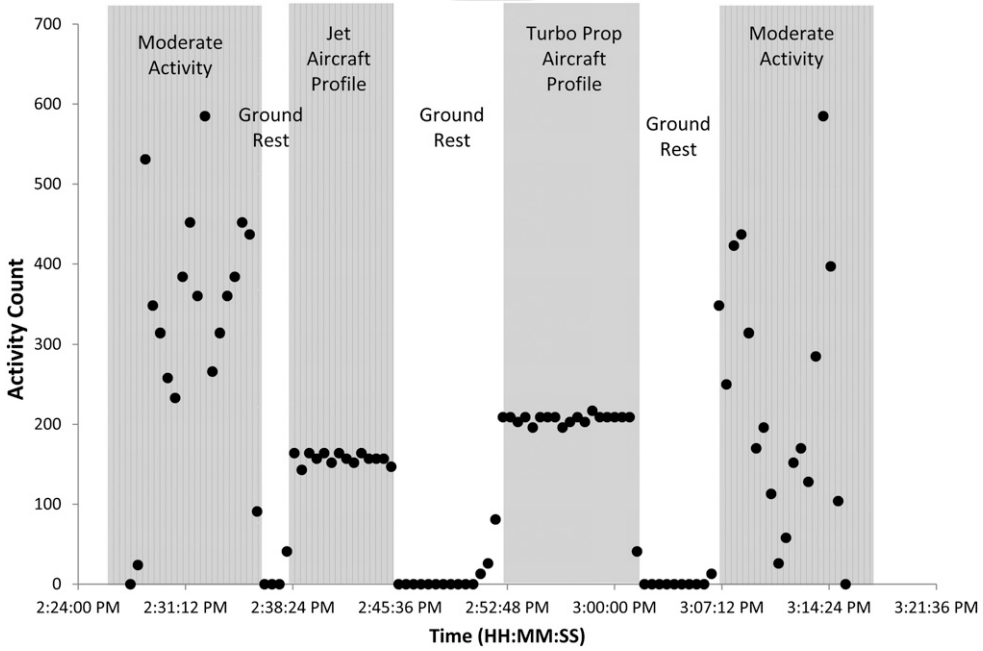

Fig. 3. Activity count recording from actigraph vibration testing.

Altitude

The purpose of altitude testing was to determine the ability of the EUT to operate satisfactorily in expected altitude environments. The test consisted of operating and monitoring the equipment at ground level to 18,000 ft (5486 m) and then returning back to ground level. The rate of ascent was 2000 ft $\cdot$ min^{-1} (fpm) (610 m $\cdot$ min^{-1}) and the rate of descent is 5000 fpm (1524 m $\cdot$ min^{-1}). The EUT devices were set up in the chamber. A performance check was accomplished at ground level. The devices were set in a steady-state running mode and exposed to altitudes of 0–18,000 ft (0–5486 m). The EUT devices were stabilized at 2000, 4000, 6000, 8000, 10,000, 12,500, 15,000, and 18,000 ft (610, 1219, 1829, 2438, 3048, 3810, 4572, and 5486 m). They remained at these altitudes for 3 min and were observed for proper operation. The devices were then returned to ground level, where a post-altitude performance test was performed based on Method 500.5 in MIL-STD-810G (7). During exposure to the high-altitude environments, the EUT devices did not experience any susceptibilities or errors.

Rapid Decompression

This test was performed using MIL-STD-810G, Method 500.5, Procedure III (7), as guidance to verify that the EUT devices will not experience any susceptibilities or pose a risk to the aircraft, aircrew members, or the patient during or following a rapid decompression event. The procedure involved a pre-test check during which a physical and functional inspection of the test article was accomplished at ground level. The test event involved a chamber simulating the ascent to 8000 ft (2438 m) at a rate that did not exceed 5000 fpm (1524 m $\cdot$ min^{-1}) followed by a decompression to 45,000 ft (13,720 m) in 60 s while observing device performance and potential safety hazards. The altitudes were maintained for 2 to 5 min and then returned to 8000 ft (2438 m) at a rate that did not exceed 5000 fpm (1524 m $\cdot$ min^{-1}). Once stabilized, the sequence was repeated for a 7-s and a 1-s rapid decompression. The EUT devices were then returned to ground level and a physical inspection and functional check of the devices were performed.

The authors determined that there was no degradation in equipment performance during the rapid decompression testing. Physical changes to the PDA included a slight bubbling of the display screen. However, no permanent damage was observed and the EUT devices were still operational after this test. No physical changes to the actigraph were identified during this test. It was determined that the EUT devices will not pose a risk to the aircraft, aircrew members, or research participants during or following a rapid decompression event.

Explosive Atmosphere

The purpose of this test was to ensure the EUT devices do not create an ignition source in a fuel-vapor environment. The optimum fuel of choice is n-hexane because its ignition properties in flammable atmospheres are equal to or more sensitive than the similar properties of 100/130-octane aviation gasoline, JP-4, and JP-8 jet engine fuel. The devices were placed in a test chamber at ambient temperature, exposed to 10,000 ft (3048 m) above sea level equivalent, and exposed to a heated fuel air atmosphere. The EUT devices were turned on and off three times and run through a functional test. Testing was repeated at ground level (7). Personnel at the USAF Material & Engineering Test Flight, Warner Robins ALC, GA, conducted the explosive atmosphere tests. The EUT devices did not cause ignition of the fuel-vapor environment.

In-Flight Assessment

Since there were no safety concerns addressed throughout any of the STF tests, the authors deemed this test unnecessary as part of the evaluation of the EUT devices. However, based on the results of the STF process, more specifically, the vibration tests, the research team did feel that it would be valuable to understand the activity count associated with the aircraft vibrations from true flight data. Therefore, once the STF approvals were obtained, flight surgeons at USAF School of Aerospace Medicine were asked to take two actigraphs on various missions to collect sample data. The intent was to have the flight surgeon wear one device and secure the other to a stationary object during at least three flights in each aircraft of interest (C-17, C-130, and KC-135). **Fig. 4** displays an example of these data for a C-17 flight. Using data acquired from this effort, the activity count threshold to distinguish aircraft vibrations from human motion can be determined.

DISCUSSION

An important aspect of the STF process is to determine which tests within the process are pertinent to the EUT undergoing evaluation. The type of tests is selected mainly due to safety concerns and functionality. The selection is made and tailoring of the test procedure is made to create the worst case scenario (7). This determination is based on discussions between the ATL team's SMEs, the requesting agency, the test engineers, and the device user. As described in the Results section, the following tests were deemed necessary for the EUT evaluation summarized: baseline performance, aircraft vibrations, EMI, altitude, rapid decompression, and explosive atmosphere. An accurate determination of required tests results in an effective use of resources. For example, the following tests were deemed unnecessary for the EUT evaluation summarized in this article due to the reasons discussed in the subsequent paragraphs: electrical safety testing, tie-down evaluations, temperature tests, and acceleration tests.

Both devices will be used with their internal batteries; therefore, the principle investigators did not require electrical safety testing. PDAs will be fully charged before proceeding to the aircraft. Because the battery is fully encapsulated in plastic casing for both devices, testing for leakage current was deemed not required.

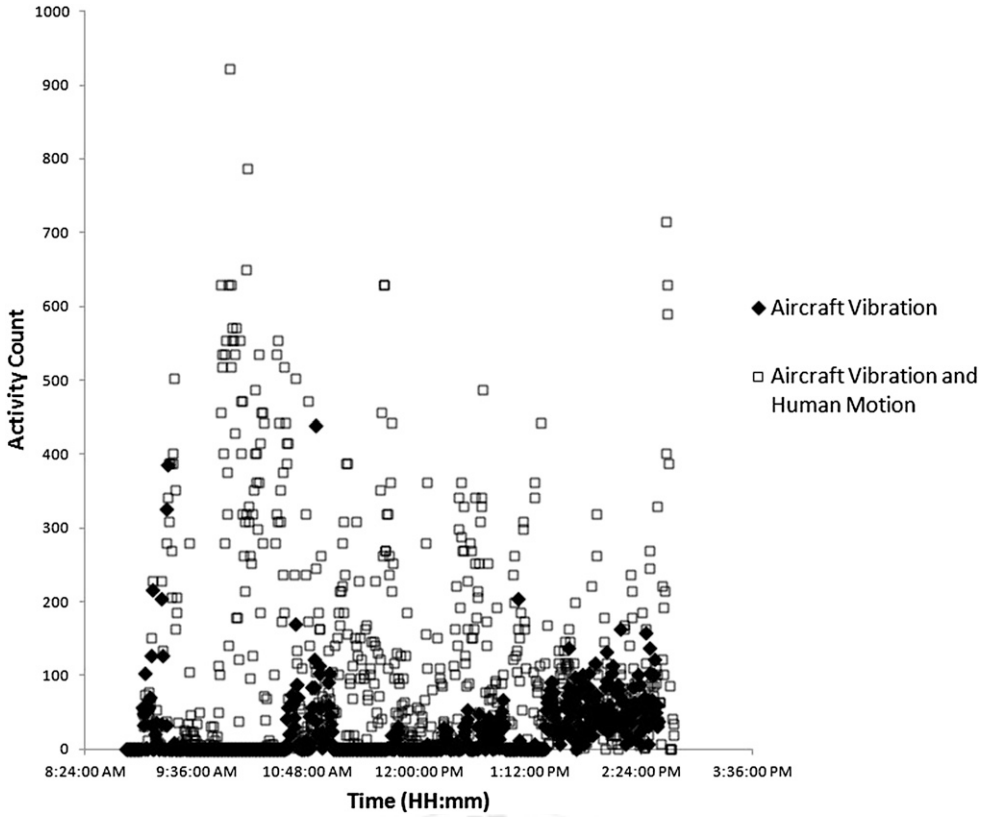

Fig. 4. In-flight activity count from actigraph data for C-17.

The ATL team's subject matter experts, AE members, and engineers determined that these devices were to be carried inside the participant's pocket (PDA) and on the participant's wrist (actigraph). Since the PDA will only be used briefly and then stowed in the participant's pocket, no tie-down evaluation was conducted.

The EUT devices will be used for a CCATT fatigue study onboard aircraft for a short period of time and there will be only 15 units used for the research study. Since the EUT devices will only be used for the relatively short duration of the research study, the authors deemed the temperature tests not required. Therefore, the emphasis in the testing of these devices was given to the tests that may pose risk to the aircraft safety.

The authors determined that the EUT devices will be placed inside the research participant's pocket and secured to the participant's wrist. Then they will be returned to the bag immediately. Additionally, the devices are both lightweight and do not pose significant risk (becoming projectile) during an acceleration event. Therefore, acceleration testing was not required [refer to the study performed by Cicek and Beisner (4) for methodology proposed for the acceleration testing of medical devices and criteria for performing an acceleration test or evaluations].

By recognizing the need to have devices STF certified early in the project planning process, ATL personnel can be contacted for advice on the timeline of the process. This information will provide the investigator with anticipated timeframes based on current workloads and resources. Certification timelines are not only dependent on the current workload and available resources in the lab, but also the number of required tests since many are conducted at various locations and coordination between test sites can be time consuming. Therefore, it is crucial to engage the ATL personnel early in the process. Additionally, when selecting equipment, it may be worthwhile for researchers to consult the list of equipment already STF certified to determine if a viable option is already available.

In conclusion, the STF test and evaluation includes a risk analysis based on the anomalies and failures observed during the tests (12). The testing process did not identify any significant risks for these EUT devices. The single limitation imposed on our analysis was the restriction preventing use of aircraft power to charge the PDA and actigraph. Accordingly, the adapters and chargers were not included in our tests. There were no other limitations associated with the use of the PDA and the actigraph identified in this study.

Based on the results of this study, the authors conclude that the PDA and actigraph are safe for use on military, fixed-wing aircraft when operated according to the manufacturers' technical manuals and subject to the aforementioned limitations and recommendations. By considering the EUT types and aircraft platforms of interest and focusing on safety risks and test performance, a final report associated with a STF recommendation letter were accomplished. As a result, the authors have currently received letters from respective aircraft Chief

Engineers approving the use of the devices aboard USAF C-130 E/H/J, C-17, and KC-135 aircraft.

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The use of brand names is for illustrative purposes and does not imply endorsement by the Departments of the Air Force, Army, or Navy or the Department of Defense. The authors have no financial interest in any commercial or Government devices mentioned herein. The opinions expressed in this paper are those of the authors and do not necessarily reflect the views of the U.S. Air Force, Department of Defense, or the U.S. Government.

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